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PDUFA
FDA AND STAKEHOLDERS PUBLIC MEETING
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Remarks
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I first would like to thank the FDA for convening this meeting, for providing an opportunity for patients and consumer advocates to comment on the past and future of PDUFA and for inviting me to be a member of this consumer panel today.

In the Federal Register notice of this meeting the FDA posed a series of questions for the panelists to address today. I would like to suggest that the most important question posed for discussion is somewhat buried in the last sentence of question #1 which reads as follows: "In addition, what do you see as the downside of a regulatory agency like FDA collecting user fees and what remedies would you suggest for the future." The FDA has said it very politely - I would rephrase the question to ask whether we think that PDUFA has created an irreconcilable tension between the agency's responsibility to protect the public health through regulation and oversight and its need to satisfy the demands of the regulated industry that increasingly pays the piper.

The FDA maintains that while the shortening of the traditional arm's length relationship between the agency and the industry it regulates may create the perception of a conflict of interest, there is

an industry skilled at getting its way.

The principle of an arms-length, conflict-free regulator is critical when trying to oversee an industry which is staggeringly profitable and as a result has a big incentive to use its wealth-derived power to influence the political process. The industry's anti-regulatory agenda has also been well served by a decade in which government-bashing is popular and free-marketers drive public policy. The FDA's approval process is the lone shield that the public must rely for protection from the unbridled enthusiasm of industry for bringing new products to market - and that shield must be constructed by processes which embody the highest degree of scientific integrity possible. It is my belief that to extend PDUFA after 2002. would not be in the public interest. If PDUFA does not continue past 2002, it will then be the responsibility of the Congress to provide sufficient support all of FDA's regulatory activities through the regular budget process at levels that assure that the public health is well served when new drugs are marketed. If Congress fails to assure that the public is protected from new drugs that are not safe, not efficacious or both, then it needs to be held accountable for the harm that is caused.

Imbedded in all the questions posed by the FDA are some fundamental assumptions that I might ungenerously characterize as having little or no science evidence for support. Foremost is the implicit assumption that making new drugs available more quickly is by definition in the public interest. While the public health benefits may be clear when a new drug is indicated for a serious or life-threatening condition which has previously been refractory to treatment, or when the available treatments are so toxic as to be of little value, that clarity disappears when the new drug is a "me-too" or "me-too" like product or is for a minor condition. Unfortunately, many of the

whose bureaucratic ineptitude was responsible for the deaths of patients whose only mistake was they were not living in Europe.

Its easy to understand why the agency, after decades of such criticism, might embrace PDUFA as a palliative solution to their pain - and be content with "success" as defined by meeting internally-set performance goals measured by the time it takes to get new drugs to market.

The theme of the FDA as an obstacle to therapeutic progress reappeared with considerably more vitriol during the early years of the HIV/AIDS epidemic. The demonstrations by ACT-UP and others were dramatic, emotional and rightfully forced the agency to reorder its priorities. But that does not mean that the amazing and rapid progress that occurred in managing HIV/AIDS should be seen as proof of the benefit of PDUFA to the public health. In fact, many of the new drugs that radically changed the prognosis for people with AIDS were already in the NDA process prior to 1993.

I would argue that the performance goals by which we measure the success or failure of PDUFA must be radically altered. Speedier drug approval clearly benefits industry; in some cases it may benefit patients or specific populations, but in most cases there is no such evidence. It is therefore inappropriate for the agency to so narrowly define its objective and to settle on one which is not evidenced-based.

The FDA's objective should be to improve the public health through its oversight and regulation of prescription drugs, biologics and devices. Its self-evaluation and how it defines performance measures should focus on how well its activities improve the well being of those who are sick and disabled. The agency must resist easy but risky solutions to its long-standing problem budgetary